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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/064,001

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Yinghui Dan

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EXAMINER

ROBINSON, KEITH O NEAL

ART UNIT

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/064,001	<b>Applicant(s)</b> DAN ET AL.	
	<b>Examiner</b> KEITH O. ROBINSON	<b>Art Unit</b> 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 May 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 August 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. In the interview conducted April 16, 2009, it was agreed that the Examiner would re-open prosecution of the instant application. Thus, the finality of the rejection of the last Office action, mailed February 3, 2009, has been withdrawn.

2. Claims 1-16 are under examination.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhong et al (Planta 187: 483-489, 1992), in view of Bowen et al (U.S. Patent No. 5,736,369, April 7, 1998), in view of Cheng et al (Plant Physiology 115: 971-980, 1997),

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Bartok et al (Plant Cell, Tissue and Organ Culture 22: 37-41, 1990), in view of Weeks et al (Plant Physiol 102: 1077-1084, 1993).

The claims read on a method of producing multiple transgenic wheat plants from a single explant comprising (a) providing an explant presenting a plurality of meristems; (b) culturing said explant in a first multiple bud inducing media suitable for inducing production of a plurality of buds from at least one of said meristems; (c) introducing exogenous DNA into more than one of said plurality of buds; (d) removing said plurality of buds from said first media and transferring said plurality of buds to a second media suitable for induction of elongation of said buds into shoots; (e) harvesting and transferring said shoots to a culture medium that promotes root development; and (f) culturing said transferred shoots to produce multiple transgenic wheat plants.

With regard to claims 1 and 13, step (a), Zhong et al teach providing an explant presenting a plurality of meristems. See, for example, page 483, 2<sup>nd</sup> column, 2<sup>nd</sup> paragraph to page 484, 1<sup>st</sup> column, lines 1-11 where it teaches surface-sterilization of seeds and aseptic germination of seeds on MS medium in Petri dishes in darkness at 24 degrees Celsius; excising a portion of young leaf and stem immediately below the leaf primordial and culturing said portion on MS basal medium; shoot tips cultured on medium and multiple shoot clumps arising from explants.

In addition, Zhong et al also teach culturing said explant in a first multiple bud inducing media suitable for inducing production of a plurality of buds from at least one of said meristems. See, for example, page 484, 2<sup>nd</sup> column, 1<sup>st</sup> paragraph of 'Results' of the Zhong et al reference where it teaches a basal medium, MS, containing BA (a

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cytokinin, as evidenced on page 7, paragraph 0034 of the specification) and 2,4-D (an auxin, as evidenced on page 7, paragraph 0034 of the specification). Also, see, for example, page 484, Figure 1 where it depicts culturing explants in a multiple bud inducing media. Zhong et al also teach "[o]ur work shows that the corn-shoot meristem can be committed to form either clumps of multiple shoots or somatic embryos in vitro by manipulating the concentrations of BA [cytokinin] and 2,4-D [auxin] in the culture medium" (see page 488, 1<sup>st</sup> column, last paragraph).

With regard to claims 1 and 13, step (b), Bowen et al teach culturing explants in a multiple bud inducing media. See, for example, column 7, lines 62-65 where it states, "a shoot multiplication medium will utilize a cytokinin, such as Kinetin, BAP, Thidiazuron or Zeation, at a concentration between 0.5 and 10 mg/l...[and] [a] low level of auxin also may be required in some genotypes". The specification teaches that a multiple shoot inducing media comprises "a basal plant tissue culture media supplemented with a cytokinin and an auxin" (see page 6, paragraph 003).

With regard to claims 1 and 13, step (c), Bowen et al teach introducing exogenous DNA into a plurality of meristems. See, for example, column 2, lines 45-46 where it states, "foreign DNA can be introduced into a plurality of meristems, at least some of which differentiate...to form a plurality of plantlets.

With regard to claims 1 and 13, step (d), Zhong et al teach removing said plurality of buds from said first media and transferring said plurality of buds to a second media suitable for induction of elongation of said buds into shoots. See, for example,

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page 484, 1<sup>st</sup> column, 2<sup>nd</sup> and 3<sup>rd</sup> paragraphs where it teaches inducing adventitious shoot formation by transferring shoot-tip explants to MS basal medium.

With regard to claims 1 and 13, step (e), Cheng et al teach harvesting and transferring shoots to a culture medium that promotes root development. See, for example, page 972, 2<sup>nd</sup> column, 2<sup>nd</sup> paragraph where it teaches young shoots were transferred to a regeneration medium for further growth and selection.

With regard claims 1 and 13, step (f), Zhong et al teach culturing transferred shoots to produce multiple transgenic wheat plants. See, for example, page 484, Figure 1 where it teaches rooted corn plants produced after shoot development.

With regard to claims 2-6, Bowen et al teach culturing explants in a multiple bud inducing media. See, for example, column 7, lines 62-65 where it states, "a shoot multiplication medium will utilize a cytokinin, such as Kinetin, BAP, Thidiazuron or Zeation, at a concentration between 0.5 and 10 mg/l...[and] [a] low level of auxin also may be required in some genotypes". The specification teaches that a multiple shoot inducing media comprises "a basal plant tissue culture media supplemented with a cytokinin and an auxin" (see page 6, paragraph 003).

With regard to claim 7, Zhong et al teach plurality of meristems containing the scutellar node. See, for example, page 483, 2<sup>nd</sup> column, last paragraph where it teaches "[t]he position of the shoot tip of the seedling inside the coleoptile could be determined by the localized enlargement of the seedling at the junction of mesocotyl and coleoptile". The specification teaches, "mesocotyl refers to the internode between and including the scutellar node, and the coleoptile" (see page 5, paragraph 0029). The specification also

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teaches “[m]eristem tissue is a tissue that produces cells that undergo differentiation to form mature tissues” (page 5, paragraph 0029). It would be obvious to one of ordinary skill in the art that meristematic tissue is inherent in the explants taught by Zhong et al.

With regard to claim 8, Bartok et al teach wheat mesocotyl explant. See, for example, page 39, Figure 2 where it teaches mesocotyls of mature wheat embryos.

With regard to claims 9, 10 and 16, Weeks et al teach exogenous DNA comprising a nucleic acid encoding a protein conferring resistance to a selection agent, selecting for plants containing the protein and introduction of said DNA via biolistic particle bombardment. See, for example, page 1078, 1<sup>st</sup> column, last paragraph where it teaches exogenous DNA, namely the *bar* gene that encodes the enzyme PAT which inactivates phosphinothricin, the active ingredient of the herbicides bialophos and Basta. See, for example, page 1079, 1<sup>st</sup> column, 3<sup>rd</sup> paragraph where it teaches a selection method based on spraying transformed wheat plants with herbicide to determine which wheat plants were resistant. See, for example, page 1078, 2<sup>nd</sup> column, 2<sup>nd</sup> paragraph where it teaches introduction of DNA via biolistic particle bombardment.

With regard to claims 11 and 15, Bowen et al teach introducing exogenous DNA into cereal plants via biolistic particle bombardment. See, for example, column 19, lines 41-46.

With regard to claims 12 and 14, Cheng et al teach introduction of exogenous DNA into wheat via *Agrobacterium*-mediated transformation. See, for example, page 971, last paragraph to page 972, 2<sup>nd</sup> column, 2<sup>nd</sup> paragraph.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of Applicant's invention to combine the teachings of the above cited references to produce a method of producing multiple transgenic wheat plants from a single explant.

One of ordinary skill in the art would have been motivated to combine these teachings because Bowen et al teach "foreign DNA can be introduced into a plurality of meristems...to form a plurality of plantlets" (see column 2, lines 45-47). Thus, one of ordinary skill in the art would be motivated to produce transgenic plants from an explant.

In addition, one of ordinary skill in the art would have reasonable expectation of success based on the success of Zhong et al in producing "[a]bout 20-50 shoots...per shoot-tip explant within four weeks of culture" (see page 486, 1<sup>st</sup> column, last line to 2<sup>nd</sup> column, 1<sup>st</sup> line). Though Zhong et al teach multiple corn plants produced from a single explant, one of ordinary skill in the art would expect that multiple wheat plants would also be produced from a single explant because Bowen et al teach that maize and wheat are monocotyledonous plants (see, for example, column 1, lines 30-32); thus, one of ordinary skill in the art would appreciate that methods used for maize can be used for wheat.

### ***Obvious Type Double Patenting***

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140



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F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claim 1 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 7 of U.S. Patent No. 5,631,152.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of said patent read on a method for producing transformed wheat comprising culturing of plant tissue, introducing exogenous DNA, and culturing shoots to produce plants wherein the steps are similar to those of the instant application.

### ***Conclusion***

8. No claims are allowed.

### ***Contact Information***

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KEITH O. ROBINSON whose telephone number is

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(571)272-2918. The examiner can normally be reached Monday – Friday, 8:00 a.m. - 4:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Keith O. Robinson  
/David H Kruse/  
Primary Examiner, Art Unit 1638